REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1, 3-5, 19, and 20 are currently under consideration. Claims 3, 4, and 5 are amended without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

The Examiner is thanked for indicating that the finality of the previous Office Action is withdrawn. The Examiner is also thanked for withdrawing the rejection of claims 1, 3-5, 19 and 20 under 35 U.S.C. §102 and the previous rejection of claims 1, 3-5, 19 and 20 under 35 U.S.C. §112, first paragraph.

It is submitted that the claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply to clarify the scope of protection to which Applicant is entitled. Support for amended claims 3-5 can be found, for example, in Example 6 of the specification.

II. REJECTIONS UNDER 35 U.S.C. § 112 ARE OVERCOME

Claims 1, 3-5, 19, and 20 are under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The rejection is respectfully traversed.

According to the Court of Appeals for the Federal Circuit in the case of *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988),

> Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. 'The key word is undue, not experimentation.' The determination of what constitutes undue experimentation in a given case requires the application of standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a considerable

> amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed ... [Citations omitted]. *Id.* at 1404.

Determining whether undue experimentation is required to practice a claimed invention turns on weighing many factors summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), for example: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples of the invention; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims.

Thus, it is respectfully submitted that for a proper Section 112, first paragraph, lack of enablement analysis, an Office Action must show that the *Wands* factors are not met. Simply, it is respectfully asserted that the lack of enablement rejection fails to provide a fact based analysis using the *Wands* factors that supports the proposition the claimed invention require **undue** experimentation.

The Examiner is respectfully reminded that a specification need not contain any example of the invention, as the issue is whether the disclosure enables one skilled in the art to practice the invention without undue experimentation. *In re Borkowski*, 422 F.2d 904, 164 USPQ 642 (CCPA 1970). Simply, a determination that undue experimentation is necessary to practice the invention does not necessarily follow from a lack of examples in the specification. And, the Examiner is further respectfully reminded that an applicant need not describe all actual embodiments of a claimed invention.

The Office Action asserts that while the specification does provide enablement for a transgenic mouse exhibiting Nasu-Hakola disease, it does not provide enablement for a transgenic mouse exhibiting a neuropsychiatric disorder selected from the group consisting of dementia, schizophrenia, schizotypal personality disorders, obsessive-compulsive disorder, or Tourette's syndrome. The Office Action contends that "neither the art nor the specification provides guidance that the claimed mice are models for the broad scope of neuropsychiatric disorders other than Nasu-Hakola," and cites references that allegedly mention different etiologies and pathologies for dementia.

In response, claims 3-5 are clarified to recite that the disorders are "associated with disruption in DAP12 gene function." Accordingly, one skilled in the art is enabled to practice the invention as disclosed in the instant claims without undue experimentation.

Firstly, one skilled in the art would not be subjected to undue experimentation due to the breadth of the instant claims. These claims, which recite that the psychiatric disorders are associated with disruption in DAP12 gene function, refine the scope of the present invention and clarify the scope of the neuropsychiatric disorders. As such, the instant claims overcome the Office Action's contention that the claims "are not enabled for its fullest breadth".

Secondly, the specification provides working examples which sufficiently enable and provide guidance for a skilled artisan to practice the instant invention and obviates the necessity for additional experimentation. The examples clearly disclose the generation of transgenic mice with a homozygous disruption in the DAP12 (Example 1), the development of hypomyelinosis in the central nervous system of the transgenic mice (Example 3), the relationship between DAP12 expression and myelinogenesis (Examples 4 and 5), and the impaired sensorimotor gating in the transgenic mice which is symptomatic of neuropsychiatric disorders (Example 6). Therefore, one skilled in the art is enabled by the specification to attain the transgenic mouse model and, consequently, the Office Action does not provide evidence that the instant invention would require undue experimentation due to working examples, amount of guidance presented, or quantity of necessary experimentation.

Finally, the state of the art refers to an association between DAP12 and myelination in the thalamus, and neuropsychiatric disorders. The Examiner is respectfully requested to consider and make of record the article by Schmitt et al. titled "Altered thalamic membrane phospholipids in schizophrenia: a postmortem study" published in Biol Psychiatry 56: 41-45, 2004, which is cited on the accompanying Supplemental Information Disclosure Statement and PTO-1449. Schmitt et al. mentions decreased myelination of neurons in the thalamus of schizophrenic patients. The Office Action cites references that refer to dementia associated with tau mutations and Parkinson's disease, but the instant claims disclose dementia associated with disruption in DAP12 gene function. Consequently, the Office Action does not provide evidence that the instant invention would require undue experimentation due to the state of the art.

Therefore, there is a failure to provide a factual showing that the present application is not enabled. Absent factual evidence corresponding to the *Wands* factors above, the Section 112

rejection is improper and must be withdrawn.

Accordingly, reconsideration and withdrawal of the Section 112 rejections is respectfully requested.

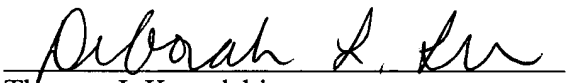
REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview with the Examiner and SPE are respectfully requested and the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: 

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